

REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

As correctly indicated in the Office Action Summary, claims 1-20 are currently pending. Claims 11 and 20 stand withdrawn as directed to non-elected subject matter. Applicants note with appreciation that the outstanding Office Action of July 29, 2004 replaces the Office Action of April 22, 2004, which is withdrawn by the Examiner.

Rejections Under 35 U.S.C. § 102

Claims 1 and 7-10 stand rejected under 35 U.S.C. § 102(b), as purportedly anticipated by U.S. Patent No. 5,516,670 ("the '670 patent"). The '670 patent purportedly discloses the use of an alternating magnetic field and a field strength of 500 gauss. Applicants respectfully traverse.

Applicants submit that the '670 patent fails to recite every element of the presently claimed invention, as amended herein. To anticipate a claim, a single prior art reference must teach each and every element of the claimed invention. See M.P.E.P. § 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986).

Independent claim 1 is directed to a method for introduction or extraction of bioparticles into/from biological membrane-enveloped structures. This method comprises applying a magnetic *alternating* field to a sample, comprising biological

membrane-enveloped structures and magnetically susceptible particles. An increase of the thermal and/or kinetic energy of the magnetically susceptible particles causes the formation of pores in said biological membrane-enveloped structures. The pores allow the introduction or extraction of bioparticles into/from the biological membrane-enveloped structures.

Thus, rejected claims 1 and 7-10 are directed to subject matter wherein the magnetic field applied to the sample is an alternating magnetic field. By way of clarification, Applicants refer to pages 2 and 3 of the present specification, which note that the sample is subjected to an alternating magnetic field (see present specification, page 2, line 27 and page 3, lines 27-37). The '670 patent fails to recite this claimed element of the present invention.

The alternating magnetic field of the present invention is very different from the disclosure of the '670 patent. The present Office Action states that the '670 patent discloses exposing particles to a "non-uniform magnetic field and optionally pulsing the field". However, the '670 patent does not disclose an alternating field. Specifically, Applicants refer to columns 2 and 3 of the '670 patent, which disclose the use of non-uniform, converging magnetic fields (column 2, lines 61-64 and column 3, lines 49-53). This is not the same as the alternating magnetic field of the present invention. The particles of the '670 patent are accelerated at the cell specimen surface with a non-uniform magnetic field (a field gradient). This field does not, however, *alternate direction*. Therefore the focal point is always positioned beyond the target cell.

In addition, the '670 patent fails to recite the claimed element of the present invention wherein the increase of thermal energy of the magnetically susceptible

particles causes the formation of pores in the biological membrane-enveloped structures. In contrast to the present invention, the particles recited in the '670 patent are like a small needle in that they penetrate the cellular specimens via high velocity and not by thermal energy. The present claims recite the creation of pores by use of thermal energy.

As the '670 patent fails to recite each and every element of the present invention, Applicants request that the rejection under 35 U.S.C. § 102 be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 2, 3, 12 and 16-19 stand rejected under 35 U.S.C. § 103, as purportedly unpatentable over U.S. Patent No. 5,516,670 ("the '670 patent"). The '670 patent purportedly discloses the use of an alternating magnetic field and a field strength of 500 gauss. Applicants respectfully traverse.

In order to establish a case of *prima facie* obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. See M.P.E.P. 2142. Applicants respectfully submit that these criteria have not been met in the present Office Action.

The '670 patent fails to recite all of the elements of the presently claimed invention or to provide an expectation of success or motivation to arrive at the claimed invention. As noted above, the '670 patent fails to recite an *alternating* magnetic field. The samples of the presently claimed invention are subjected to a high frequency alternating field. Thus, *the field direction is changed to the opposite*

direction but with the same magnitude. In contrast, the '670 patent discloses a particle or suspension of mono-disperse particles with a defined three dimensional structure, *i.e.*, an acicular magnetizable particle. This particle is accelerated towards the cell specimen surface with a non-uniform magnetic field, here a field gradient. This field does not alternate direction, and this is why the focal point is always positioned beyond the target cell. The field gives the particle high speed which turns the particle in a tiny projectile. The particle travels in the direction towards the focal point of the converging magnetic field. The cells can be treated with repeated pulse of magnetic field. However, the magnetic fields of the '670 patent never change direction. Therefore, the '670 patent fails to recite or even to suggest a magnetic alternating field let alone the benefits of using an alternating field.

By exposing the cells of the present invention to an alternating magnetic field, *i.e.*, a field with alternating direction instantaneous heating of the medium surrounding the magnetically susceptible particle is possible (see present specification, page 6, lines 13-24). This benefit is not disclosed or suggested in the '670 reference. Without any motivation to attempt an alternating magnetic field, the skilled artisan would not arrive at the present invention.

Finally, the '670 patent does not disclose or suggest that the increase of thermal energy of the magnetically susceptible particles causes the formation of pores in the biological membrane-enveloped structures. In contrast, the particles of the '670 patent penetrate the specimens using high velocity, and not thermal energy.

In light of the above remarks, Applicants request that the rejection under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

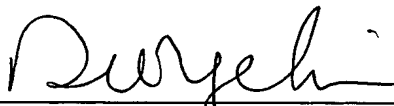
In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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